UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	V
THE CITY OF NEW YORK,	-X Case No: 24-cv-5161 (GHW)(JW)
Plaintiff,	
-against-	
ENVIROMD GROUP LLC; GT IMPORTS; KAYLA WHOLESALE, INC., d/b/a The Vapery; KLCC WHOLESALE, INC.; MV TRADING LLC a/k/a MYVAPORSTORE; PIONEER DISTRIBUTION, INC. a/k/a WEVAPEUSA.COM a/k/a SELLER SUPREME L RZ SMOKE INC.; STAR ZONE INC.; URBAN SMOKE DISTRIBUTORS; VAPE MORE INC a/k/a MORE LLC; VAPE PLUS DISTRIBUTION CORP. a/k/a G&A DISTRIBUTION;	
Defendants.	-X

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS THE SECOND AMENDED COMPLAINT AGAINST DEFENDANT KAYLA WHOLESALE, INC.

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I. PRELIMINARY STATEMENT

This action, originally commenced in the Supreme Court of the State of New York,

County of New York [Index no. 451009/2024], was removed to this Court following amendment
of the Complaint to include federal causes of action. This Memorandum of Law is respectfully
submitted in support of Defendant Kayla Wholesale Inc.'s ("Kayla") Motion to Dismiss the
Second Amended Complaint ("SAC") against it. Kayla is accused of (and requests dismissal of)
any claims asserted against it under and/or alleged violations of the Prevent All Cigarettes

Trafficking Act ("PACT Act") (15 USC 375 et seq), the Tobacco Control Act (21 USC 387 et
seq.), the New York State Public Health Law ("PHL") sec. 1399-II, and sec. 17-715 of the New

York City Administrative Code ("NYCAC"). Kayla also requests dismissal of the SAC's cause
of action against it alleging Public Nuisance.

This motion is made pursuant to FRCP 12(b)(6). Kayla is one of several defendants the City of New York has confusingly and prejudicially lumped together in an action alleging unlawful sales of flavored vaping products. The SAC, even as amended, is difficult to parse from the perspective of an individual defendant. Beginning with ¶1, which alleges, collectively, that defendants have violated every federal, state and city law, and continuing to paragraphs such as ¶154, which alleges that all sales of each of the defendants were sales to consumers, the SAC fails to specify the allegations against Kayla in a manner that should survive dismissal. Instead, the SAC is improperly and prejudicially attempting to create guilt by association.

Moreover, as more fully set forth below, the Complaint should be dismissed against Kayla to each and every extent that, among other deficiencies, : (i) Kayla's alleged actions predate some of the statutes invoked in the SAC; (ii) Kayla engaged in distributor to distributor sales that did not violate the law; (iii) the action is contrary to applicable enforcement

mechanisms for the statutes at issue including but not limited to the FDA's enforcement scheme, a significant part of which has been ruled to be arbitrary and capricious, and is awaiting U.S. Supreme Court review in the Court's next term; (iv) New York City lacks jurisdiction to enforce federal or state laws implicated in the AC; (v) New York City may not enforce the Public Health Law or the New York City Administrative Code in this manner because there are administrative procedures for enforcement of these laws; (vi) in whole or in part, the SAC's allegations are beyond applicable statutes of limitation; (vii) the allegations of public nuisance are insufficient to withstand dismissal.

II. ALLEGATIONS AGAINST KAYLA

Kayla is a general merchandise wholesaler that sells items including glass items, rolling papers, trays, condoms, toothpaste, batteries and other items. During the COVID pandemic, Kayla's major sales were of personal protective equipment to nursing homes and other medical facilities, and following the pandemic, Kayla resumed its sales of other items.

The SAC incorrectly alleges that Kayla's principal place of business was within the City of New York, County of Kings. [SAC ¶ 18] Its actual principal place of business is and was in Jericho, New York, in the County of Nassau. More importantly, despite the SAC's attempt to create the impression of widespread sales, Kayla is accused of a very limited number of actual sales, the majority of which predated the effective dates of statutes in issue. The SAC also acknowledges that a website associated with Kayla which allegedly offered flavored e cigarettes for sale, has been shut down. [SAC ¶ 74]. The SAC, at ¶ 73, alleges seven sales to a distributor known as Star Vape² between August of 2020 and November of 2020. It also alleges two small

¹ See New York Department of State, Division of Corporations Website apps.dos.ny.gov/publicinquiry/Entity/Display.

² Star Vape was originally alleged to have been a distributor in the state court complaint but is now alleged, without additional supporting facts, to be a "consumer" under the definitions applicable to the PACT Act.

quantity sales of product to a City investigator in March of 2024. [SAC ¶¶ 75-78]. The remainder of the SAC is rife with unsustainable allegations against Kayla that are the product of conjecture, extrapolation, and speculation as to what was allegedly sold, to whom, and when. For example, at ¶74, the SAC refers to an "internet tracking service" where, allegedly, "thousands of (unidentified) prospective e-cigarette purchasers" allegedly accessed a website (now shut down) attributed to Kayla. Allegations that unknown persons may have clicked on a website do not support violations especially when an internet search using the word "Kayla" produces dozens or hundreds of results including but not limited to a seller of Italian ices, photographers, an e-bay store, and various individuals. Kayla is also accused, upon information and belief, of shipping vapor products to persons who place orders on its (now shut down) internet site who are not licensed or registered vapor product or e-cigarette dealers, and it is further accused, upon information and belief, that each delivery of e-cigarettes to Star Vape weighed in excess of 10 pounds. [SAC ¶¶ 83,84]. Such allegations portend nothing more (or less) than a planned fishing expedition on the part of the City, which neither supports the current accusations against Kayla nor is proper, given that the SAC is the third iteration of a complaint containing serious allegations.

III. **ARGUMENT**

1. THE COMPLAINT SHOULD BE DISMISSED PURSUANT TO FRCP 12(b)(6)

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. The plausibility standard is not akin to a probability standard but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Elias v. Rolling Stone LLC, 872 F 3d 97, 104 (2d Cir. 2017) (quoting Ashcroft v. Igbal, 556 US 662, 129 S. Ct. 1937 (2009)). Here, the SAC either contains allegations that on their face must be dismissed, or lack the necessary factual allegations to maintain them. Although a Court must accept as true all factual allegations in a Complaint, this requirement is inapplicable to legal conclusions. Vaughn v. Phoenix House New York, Inc., 957 F3d 141,145 (2d Cir. 2020). Courts are not bound to accept as true a legal conclusion couched as a factual allegation and threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice. Ibekweh v. Ascend Learning, Inc., 22 CV 1587 (EDNY September 27, 2023). Here, especially as to (but not limited to) allegations against Kayla involving statutes that had not yet become effective (or had not yet been enacted) before Kayla's alleged actions, the SAC is rife with legal conclusions, conjecture, and surmise and it should be dismissed in whole or in part.

A. All Alleged PACT Act Violations Against Kayla Must be Dismissed.

1. Kayla Joins in Defenses to the PACT Act Interposed by Co-Defendants in this Matter.

Co-Defendants have previously raised defenses to the PACT Act. As held by this Court in its Order of September 12, 2024 at ECF Doc. 69, and in order to avoid detaining the Court with repetition, Kayla joins in these defenses and asserts that all PACT Act violations against it should likewise be dismissed. For the avoidance of doubt, these defenses include Plaintiff's lack of standing to enforce the PACT Act and the SAC's failure to state a plausible claim for violating the PACT Act as set forth in the Request for Pre-Motion Conference dated September 11, 2024 submitted by Co-Defendant EnviroMD Group and other defendants [ECF Doc. No. 66]; the Request for a Pre Motion Conference dated September 11, 2024 submitted by Co-Defendants Vape More and Vape Plus [ECF Doc. No. 65], and in ECF Doc. Nos. 57-1 and 30.1.

2. Kayla's Alleged Violations Pre-Dated the Effective Date of Relevant Laws

The First Claim for Relief ¶¶ 182-188, accuses Kayla of non compliance with PACT Act requirements relating to delivery sales, and invokes 15 U.S.C. sec. 375 which among other things, defines "cigarette" to include an Electronic Nicotine Delivery System (an "ENDS" product), and also defines the terms "consumer," "delivery sale," "delivery seller," and "Electronic Nicotine Delivery System." Such PACT Act allegations against Kayla relating to its 2020 alleged sales to Star Vape must be dismissed because the amendments to 15 USC sec. 375 (which, again, included ENDS products in the federal definition of cigarettes and defined what ENDS products were), did not become effective until 90 days after the December 27, 2020 passage of the amendment, or specifically, on March 27, 2021. According to the SAC itself, there were no sales to Star Vape after November of 2020, thus rendering it impossible that Kayla violated statutes enacted after that time.

Kayla is accused upon information and belief, of shipping or causing to be shipped vapor products to persons who place orders on its internet site who are neither licensed or registered agents of vapor product dealers published by the New York State Department of Taxation and Finance, nor licensed/registered persons as agents/dealers under Article 28-C of the tax law. [SAC Para. 83]. But March 27, 2021 was also the effective date of amendments to the PACT Act that required (a)registration by sellers of ENDS products with the Bureau of Alcohol, Tobacco and Firearms, and (b)registration/reporting with tobacco tax administrators of states into which vape products were shipped.

Kayla is accused, upon information and belief, of making sales to Star Vape through the mail. [SAC ¶80]. But the PACT Act amendments contained in Public Law 116-120 (December 27, 2020) only required the US Postal Service to promulgate regulations clarifying the

applicability of the prohibition on mailing of cigarettes to ENDS Products, and the prohibition on mailing of ENDS products only came into being on October 21, 2021, after the promulgation of those rules. 18 USC sec. 1716E(a)(1). [86 Fed. Register 201, sec 471.5, 472.1].³

The SAC's allegations as to the Family Smoking Prevention and Tobacco Control Act, 21 USC sec. 387, and its reference to the FDA's regulatory authority over electronic cigarettes [SAC paras. 28-32] also has limited, if any, application to Kayla based on the dates of its alleged sales. The Consolidated Appropriations Act of 2022 ("CAA") amended the definition of "tobacco product" to include those that contain nicotine from any source, effective April 14, 2022. [21 USC § 321(rr)] The FDA's own regulations pursuant to the CAA were not effective until March 20, 2023.

Based on the above, any and all allegations and/or causes of action against Kayla based on alleged violations dating from before the effective date of the above statutes/amendments/regulations must be dismissed.

3. The SAC Should be Dismissed to Each Extent the FDA Failed to Follow its own Administrative Enforcement Scheme

Even if the PACT Act had or has application to Kayla, which is denied, the SAC concedes, at ¶¶ 49 and 51, that the usual enforcement mechanism of the FDA includes forwarding warning letters to alleged violators of the PACT Act. Indeed, by the City's own allegations, hundreds, if not thousands of these letters have been sent to manufacturers and retailers, affording them with an opportunity to defend themselves and to avoid civil penalties, among other things. Nowhere in the SAC is it alleged that such a letter was ever forwarded to

³ Any accusation that Kayla violated PHL provisions regarding marking of packages containing vapor products may be pre-empted by 15 USC 376a(e)(5)(A)(iv), which provides in relevant part, that no state or local government may enact or enforce any law relating to delivery sales that restrict deliveries of cigarettes or smokeless tobacco to consumers by common carriers or other delivery services by requiring that packages contain any particular labels, notice, or markings. Such accusations are contained in SAC paras. 76 and 78.

Kayla. The action should be dismissed against Kayla to any extent that this attempted enforcement of federal state and/or city laws is not in compliance with administrative procedures. As will be set forth in more detail below, this action is also contrary to statutory administrative mechanisms required to be employed for enforcement of New York State and New York City laws.

4. The FDA's Regulatory Scheme for E-Flavored Cigarette Products Has Recently Been Called into Question and Will Be Reviewed by the US Supreme Court, Possibly Rendering the Allegations in the SAC Moot

The SAC and the enforcement scheme for the ENDS Products at issue are largely based on the absence of FDA approval of these products. [SAC ¶¶ 10, 32,154]. To be sure, the Tobacco Control Act requires tobacco product manufacturers to obtain FDA (pre market) authorization before marketing any "new" tobacco product and that the FDA must find that marketing of the product would be appropriate for the protection of public health in order for approval to be given. [SAC ¶ 29, 30]. But, contrary to any allegations otherwise that may be inferred, the FDA's standards for denial of approval of flavored e-cigarettes (including, possibly, the products offered by Kayla) may be faulty, and will soon be reviewed by the US Supreme Court. Since the FDA's approval or rejection of these products lies at the heart of this matter, respectfully, the Court should hold this matter in abeyance until the Supreme Court rules on whether the FDA's procedures for granting or denying approval were arbitrary or capricious.

In *Wages and White Lion Investments, LLC v. Food and Drug Administration*, 90 F4th 357 (5th Cir. 2024), the Fifth Circuit, noting that the FDA had, over several years, "sent manufacturers of flavored e-cigarette products on a wild goose chase," set aside certain marketing denial orders issued by the FDA as arbitrary and capricious, and remanded them to the FDA. In so ruling, the Court decried the FDA's having given manufacturers instructions on what

information was needed for the approval process and then its having imposed new testing requirements without notice, resulting in the denial of all one million flavored e-cigarette applications. The Court deemed it "even worse" that the FDA, after requiring submission of detailed marketing plans as a critical part of the applications, rejected the applications without reviewing the marketing plans, citing an Eleventh Circuit case, Bidi Vapor LLC v. FDA, 47 F.4th 1191 (11th Cir. 2022), as having held that the FDA's refusal to even read marketing plans was an arbitrary and capricious failure on the agency's part. In so ruling, the Court also noted the prohibition on post hoc rationalizations, and stated that even if it looked past the former, the agency's post hoc statements underscored its arbitrariness. The Court noted that at oral argument, the FDA contradicted the administrative record and stated that it had reviewed "summaries" of the applicants' marketing plans, and in addition, had excluded menthol flavored e-cigarettes from its definition of "flavored products," and has subsequently approved these products. The SAC in this matter contains verbose allegations of the alleged dangers of e-cigarettes. Addressing such concerns, the Fifth Circuit noted that the FDA had turned around and denied petitioners' applications because of the absence of certain studies, but when the petitioners had submitted voluminous and robust scientific studies to show e-cigarettes induce adults to switch from smoking (deemed a life saving measure), the FDA categorically rejected that data as irrelevant because it did not show that flavored e-cigarettes promoted more switching than unflavored ones. Based on the FDA's violation of the foregoing and other administrative law principles, the Court held the agency acted unlawfully.

A determination of the alleged dangers of e-cigarettes is not a *fait accompli*, contrary to the impressions otherwise that may be drawn from the SAC. *Critically, the US Supreme Court has granted certiorari [Docket no. 23-1038, July 2, 2024], to decide whether the Court of Appeals*

docketed for argument in the Court's October 2024 term. Furthermore, the FDA itself has implemented additional review of marketing denial orders. Indeed, on June 23, 2022, the FDA had issued marketing denial orders to JUUL Labs for all of their products marketed in the US, based on the FDA's determinations that JUUL's applications for approval lacked sufficient evidence regarding the toxicological profile of the products. Then, on July 5, 2022, the FDA stayed the above orders pending additional review of relevant scientific issues. On June 6, 2024, the FDA rescinded the orders, based on new case law relating to marketing denial orders for other e-cigarette products and based on the agency's review of information provided by JUUL. ⁴

Respectfully, based on the questions that exist with respect to whether the bans on flavored ecigarettes were properly implemented and whether they will remain in place, this Court should, at the very least hold this matter in abeyance until the Supreme Court rules on these matters.

B. <u>Allegations against Kayla under New York State Law Must be Dismissed</u> 1. The City's Claims for Violation of the New York Public Health Law Should be Dismissed

Kayla joins in, and adopts and incorporates by reference its Co-Defendants' arguments that the City's claims for violation of the New York PHL fail for the reasons set forth in ECF Document nos. 30.1, 57.1, 65, 66. Any and all allegations of such violations asserted against Kayla should be dismissed.

2. This Lawsuit is Contrary to PHL Enforcement Provisions

The relevant sections of the New York Public Health Law indicate that enforcement is through hearings conducted by an enforcement officer. PHL sec. 1399-aa(1) defines "enforcement officer" as the officer designated pursuant to Article 13 E of that chapter to enforce

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⁴ "Update on FDA's Scientific Review of JUUL Product Applications", June 6, 2024.

that Article and hold hearing pursuant thereto. That section further provides that in cities with populations of more than one million, an enforcement officer is an officer or employee of a city agency that is authorized to enforce local laws regulating sale of tobacco products to minors.

PHL sec. 1399-ee(1) provides that hearings shall be conducted with respect to violations of Article 13-F entitled "Regulation of Tobacco Products, Herbal Cigarettes, and Smoking Paraphernalia; Distribution to Minors." Included within that Article are definitions for electronic cigarettes and vapor products (sec. 1399-aa(13) and (17)). No provision of the PHL relating to electronic cigarettes or flavored vaping products states that these sections may be enforced by means of a court action.

C. <u>Kayla's Alleged Violations of the NYC Administrative Code sec. 17-715 Should</u> be Dismissed

1. Kayla joins in, adopts and incorporates by reference its Co-Defendants' arguments as to the failure of the City's claims for violations imposed by the New York City Administrative Code 17-715. See ECF Doc. Nos. 66,65, 57.1, and 30.1.

3. Any Allegations Against Kayla that Pre-Dated Relevant Administrative Code Provisions Must be Dismissed

The SAC alleges that Kayla's website offered flavored e cigarettes for sale in New York City beginning in June of 2019. For the reasons set forth earlier, this is a conclusory and speculative accusation that should not withstand dismissal to any extent that it is alleged as a violation of law. But this accusation fails for another reason. The proscriptions on sales of flavored tobacco products, flavored electronic cigarettes, and flavored e liquids contained in sec 17-715 became effective on July 1, 2020. To any extent that Kayla's alleged actions preceded this effective date, they must be dismissed.

4. A Lawsuit Pursuant to Section 17-715 is Precluded by an Administrative Enforcement Mechanism

Each of these allegations should also be dismissed because this action is an improper means of enforcing the New York City regulations. NYC Admin Code sec. 17-717 contains a provision providing that the Department of Consumer and Worker Protection and/or the Department of Finance shall enforce the provisions of this subchapter. Further, the section provides that a proceeding to recover a civil penalty (as this matter does) must be commenced by the service of a notice of violation returnable to the NYC Office of Administrative Trials and Hearings (OATH office). Notice of a claimed violation constitutes a defendant's notice of the violation charged. Here, no such notice was filed, as required by the Administrative Code. The alleged violations referenced in the Complaint are administrative matters which were required to be enforced, if at all, in the proper agencies.

The City has itself evidently recognized that its attempted enforcement of e-cigarette laws in this matter is problematic in that it cites provisions of the General City Law and New York City Charter in an attempt to establish standing. The City's efforts in this regard fail. NYS General City Law sec. 20(22) (contrary to the Amended Complaint's allegation otherwise) is a section primarily granting powers to cities to regulate by ordinance or local law any matters within the powers of the city. Here, regulation of e cigarette products is exactly the object of NYC Admin. Code sec 17-715, but this does not mean that the law may be enforced in this manner especially when the Administrative Code provides otherwise. Neither does The New York City Charter sec. 394 authorize this action, contrary to the SAC's allegation otherwise. The cited Charter section provides, in relevant part, that "except as otherwise provided in this chapter or other law, the corporation counsel shall have the right to institute actions in law...to.. defend and establish the rights, interests, revenues, property, privileges, franchises, or demands of the

city..or to enforce the laws."(emphasis added) Here, the above provision of the NYC Admin.

Code otherwise provides that e-cigarette matters are to be adjudicated administratively. The City should be required to follow its own regulatory scheme and the claims based on the New York

City Administrative Code should be dismissed.

D. The Public Nuisance Claim Must be Dismissed⁵

The SAC additionally fails to allege facts against Kayla in support of its Public Nuisance cause of action and must be dismissed. To succeed on a public nuisance claim, Plaintiff must show that Defendant's conduct "amounts to substantial interference with the exercise of a common right of the public," thereby endangering or injuring the property, health, safety or comfort of a considerable number of persons." *In re Methyl Tertiary Butyl Ether ("MTBE")*Prods. Liab. Litg., 725 F.3d 65, 121 (2d Cir. 2013) (quoting 532 Madison Ave. Gourmet Foods v. Finlandia Ctr., 750 N.E.2d 1097, 1104 (N.Y. 2001)). Plaintiff must allege that the conduct or omissions of Defendant created, contributed to, or maintained a public nuisance. See Hicksville Water Dist. V. Phillips Elec. North Am. Corp., No. 17-CF-4442 (ADS) (ARL), 2018 U.S. Dist. LEXIS 53342, at *19 (E.D.N.Y. March 29, 2018).

Here, the Complaint alleges several proscriptions against marketing e-cigarette products to minors [Amended Complaint, ¶ 198], none of which proscriptions are even attempted to be made against Kayla, nor can they be. Presumably, the "City Agent" who approached Kayla for a purchase was not a minor under the age of 18 and this is certainly not alleged in the SAC.

⁵ Kayla adopts and joins in its Co-Defendants' arguments in this regard as well as the material set forth above.

Moreover, the Complaint's allegations of a purported "hazardous waste problem from improper disposal in public places of devices containing chemicals that can be toxic or fatal if ingested in concentrated forms," and allegations of a similar, general sounding nature [SAC, Paras 200-204] are nothing more than illusory, speculative allegations that are devoid of factual averments supporting claims against Kayla in this regard. As to Kayla, the Complaint contains only sparse and remote in time allegations. To any extent that the Complaint has been interposed in the hopes of discovering further alleged violations, it is a fishing expedition, not favored in the law. See, e.g. *Dritsas. v. Anchem Products, Inc.*, 169 AD3d 526 (1st Dept 2019).

E. PHL, NYC ADMINISTRATIVE CODE, AND PUBLIC NUISANCE CLAIMS SHOULD BE DISMISSED BECAUSE THEY ARE BEYOND STATE STATUTES OF LIMITATION

CPLR 3211(a)(5) provides for dismissal of causes of action when they may not be maintained because of a statute of limitations. To any extent that any purported claim against Kayla occurred more than three years prior to April 4, 2024 (the date of original commencement of this action), it is time barred.

CPLR 214(2) provides that an action to recover upon a liability, penalty or forfeiture created or imposed by statute must be commenced within three years. Here, both PHL 1399-ll and NYC Administrative Code 17-715 impose liability and/or penalties by statute.

Pursuant to CPLR 214 (4), actions to recover damages for injury to property must be commenced within three years. As to the City's cause of action for Public Nuisance, assuming without conceding that it is properly pleaded, which it is not, any claim for damages or penalties related thereto is subject to a three-year limitations period measured backwards from the time of commencement of the action. See *People v. Juul Labs, Inc.*, 2022 NY Slip Op 32121 (Supreme

Court, New York County July 5, 2022). Here, the Complaint demands not only injunctive relief, but unspecified penalties, and the establishment of an unspecified "fund" to abate a spuriously alleged "nuisance," and any such claims should be dismissed to every extent they are time barred.

IV. <u>CONCLUSION</u>

For the reasons set forth herein, and those in the consolidated Memorandums of the Co-Defendants herein which Kayla joins, the SAC should be dismissed against Kayla Wholesale.

Dated: New York, New York September 27, 2024

Yours etc.

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